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Original Article

Removability of a Newly Developed Oral Care Gel to Simulated Dry Phlegm and Debris

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Keywords: oral health care, oral care gel, removability, prevention, aspiration pneumonia

Abstract:

Objectives: Some dependent older adults have a lot of dry phlegm and debris leading to the presence of bacteria firmly adhered to the oral and pharyngeal mucosa. This must be removed completely and safely to maintain oral hygiene and general health. We developed a new oral care gel, Okuchi-Wo-Arau-Gel® (OG) that softens dry phlegm and debris allowing them to be removed easily and safely. The aim of this study was to evaluate the removability of simulated dry phlegm and debris *in vitro* using the OG.

Methods: In this experiment, standardized bovine thrombus (test soil) was used as simulated dried sputum or residue to compare the ability of OG and three commercial gels, Viva-Jellwet® (VJ), Refrecare® (RC), and Biotene OralBalance® gel (BT), to remove bovine thrombus. The test soil was covered with 0.5 mL of each gel, which was suctioned with a probe 1 min after (Experiment I) and 10 min after (Experiment II), spreading. The test soils were photographed with a digital camera and the digital images were analyzed in Photoshop. The pixel numbers of test soil were compared after suctioning, and a decrease in pixels was calculated as the removal value. Additional apparent viscosity and pH experiments were performed to confirm the physical properties of the research gels.

Results and discussion: The OG and VJ had a significantly higher removal value than the other gels in Experiment I. The OG had a significantly higher removal value than the other gels in Experiment II. The apparent viscosity of the OG and VJ was significantly lower than that of RC and BT. The pH of the gel ranged from 6.19 to 7.15. The OG and VJ retained more water than RC and BT and penetrated the test soils more easily. Additionally, the OG component had a higher removal rate in the test soils than VJ because it contained a surfactant.

Conclusions: In this *in vitro* study, the OG exhibited a greater ability to remove test soils compared with VJ, RC, and BT. The results indicate that the OG and VJ might be more effective than other gels at removing dry phlegm and debris from the oral and pharyngeal mucosa, whereas RC and BT have better anti-evaporation properties. We think that selecting gels by purpose is one way to improve the quality of oral care.

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Introduction

Poor oral hygienic conditions adversely affect general health[1,2] and pneumonia is one of the most dangerous diseases in terms of the mortality of older adults. Oral hygienic management plays an important role in preventing aspiration pneumonia in older adults[3]. However, dependent older adults find it difficult to maintain their oral hygiene by oral care alone.

In dependent older adults, the secretion of saliva diminishes relative to a patient's general condition, lack of stimulation, or side effects associated with medication[4]. Dependent older adults who require oral care are often affected by dry mouth[5,6]. Dry phlegm and debris adhere to the oral mucosa of the hard palate and tongue in patients with dry mouth, which is not observed in healthy individuals. Because dry phlegm and debris include bacterial masses, it is necessary to remove them through oral care.

Water is frequently used during the oral care of dependent older adults. However, it flows into the pharynx easily, causing aspiration. A previous case report indicated two patients died from aspiration pneumonia after oral care using water in Japan[7]. In dependent older adults with impaired cough and swallowing reflexes, water should be avoided during oral care. We usually use gel instead of water during oral care because the viscosity of gel reduces the risk of it flowing into the pharynx.

Oral hygienic care of patients with dry mouth is difficult to perform safely and effectively because dry phlegm and debris adhere to the oral mucosa too firmly to be removed easily. Indeed, the forced removal of debris may cause mucosal injury and/or bleeding, and the consequent scratches and blood clots can cause further contamination of the oral cavity. To facilitate the removal of debris from the oral mucosa in dependent older adults with dry mouth, the adherent substances need to be softened by increasing their moisture levels.

We developed a new oral care gel, Okuchi-Wo-Arau-Gel® (OG) to reduce the risk of aspiration during oral care, and to easily soften and remove dry phlegm and debris adhered to the oral mucosa[8] in 2016. However, the removal ability of OG has not been confirmed objectively. The purpose of the present study was to evaluate the removable ability of simulated dry phlegm and debris by the OG *in vitro*.

Materials and Methods

Materials

We used OG (Nippon Shika Yakuhin Co., Ltd., Yamaguchi, Japan) and three commercially available gels: Viva-Jellwet® (VJ) (Tokyo Giken, Inc., Tokyo, Japan), Refrecare® (RC) (Bean Stalk Snow Co., Ltd., Tokyo, Japan), and Biotene OralBalance® gel (BT) (GlaxoSmithKline KK, Tokyo, Japan) in this *in vitro* study. These three gels were selected for study because they are commonly used in the medical and long-term care fields. The ingredients of the four gels are shown in Table 1.

Evaluation methods

We evaluated the removal ability of each gel using a wash evaluation kit, Test Object Surgical Instruments (TOSI) (NITI-ON, Chiba, Japan). The TOSI is a stainless-steel plate with a test soil of a bovine blood clot (Fig. 1), and one containing albumin, hemoglobin, fibrinogen, and thrombin derived from purified bovine blood. TOSI is commonly used to assess the effects of washing on medical instruments[9]. The test soil contains proteins, including albumin and hemoglobin. In addition, the exfoliated stratified squamous epithelium found on the oral mucosa contains a significant amount of dried phlegm and debris, which also consists of proteins. Therefore, in this experiment, we simulated dry phlegm and debris using the bovine blood clot on the test soil.

In this study, 0.5 mL of each gel was gently spread on the test soil on a glass plate. Then, 1 and 10 min after spreading, the gel covering the test soil was removed using a suction tube (Daiichi Medical, Tokyo, Japan) connected to a Minic DC-II suction device (Shin-Ei Industries, Tokyo, Japan) with a pressure of −30 kPa, which is the suction pressure recommended during oral hygienic care in clinical practice (Fig. 2). The tip of the suction tube was fixed in place 1 mm above the test soil. When moving the glass plate, the suction device was applied to the surface of the test soil covered with gel for 20 s. Two experiments (performed at 1 and 10 min after the application of the gel) were conducted for each type of gel. Experiment I simulated routine oral care and the test soil was suctioned off 1 min after gel placement. Experiment II simulated oral care in a severe case of dry mouth and the test soil was suctioned off 10 min after gel placement. Nineteen specimens were assessed for each test sample in each of the two experiments.

Image analysis

After the suctioning procedure, the test soils were photographed with a digital camera and the images were analyzed using Adobe Photoshop CS6 (Adobe Systems Japan, Tokyo, Japan). The positions of the camera and the TOSI were fixed and the number of test soil-related pixels in each image was quantified. The percentage removal values were determined based on the differences in pixel numbers between groups after suctioning.

Physical property tests

Physiological property tests were conducted to measure the

Table 1 Ingredients of the four sample gels

	Active ingredient	Solvent	Wetting agent	Binder	Preservative	pH regulator	Sweetener	Soluble	Fragrance	Refreshing agent	Colorant	Stabilizer
OG		Water	Glycerin Sodium hyaluronate	Hydroxyethyl cellulose Sodium polyacrylate	Sodium benzoate Cetylpyridinium chloride	Sodium citrate Citric acid	Saccharin sodium	PEG-60 hydrogenated castor oil	Fragrance (Mint type)	Thymol	Copper chlorophyllin sodium Yellow 203 Blue 1	
VJ		Water	Glycerin	Sodium alginate Hydroxyethyl cellulose	Cetylpyridinium chloride Sodium benzoate	Citric acid Sodium citrate						
RC	Hinokitiol Dipotassium glycyrrhizinate	Purified water	Concentrated glycerin Propylene glycol Sodium hyaluronate	Sodium polyacrylate Carrageenan	Sodium benzoate	Disodium hydrogen phosphate Citric acid	Xylitol	Polyoxyethylene hydrogenated castor oil	Fragrance (Honey flavor type)			Disodium edetate
BT		Water	Glycerin	Carbomer Hydroxyethyl cellulose		Sodium hydroxide	Sorbitol Xylitol					

OG, Okuchi-Wo-Arau-Gel®; VJ, Viva-Jellwet®; RC, Refrecare®; BT, Biotene OralBalance® gel.

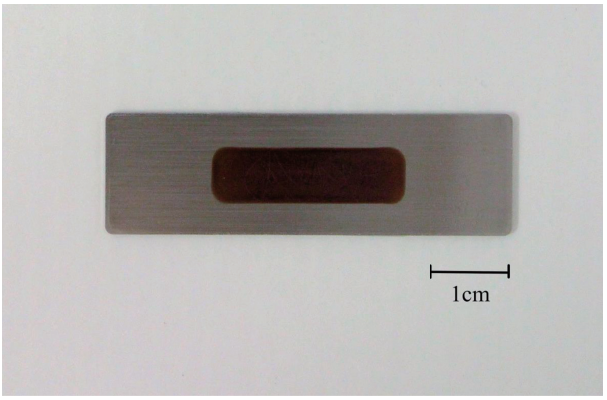

Fig. 1 Test Object Surgical Instrument (TOSI).
TOSI consists of a test soil and stainless-steel plate.

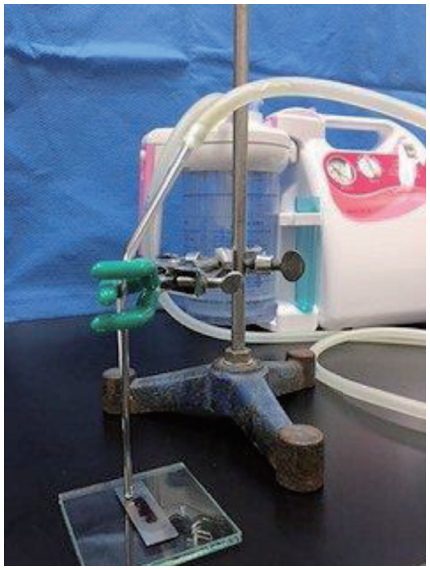

Fig. 2 Suctioning method and devices.
The samples were suctioned using a suction device and suction tube with a pressure of −30 kPa. The tip of the suction tube was fixed in place 1 mm above the test soil. While moving the glass plate, the suction device was applied to the surface of the test soil covered with gel for 20 s.

apparent viscosity and pH of the materials.

The apparent viscosity of the gels was measured in the samples at a low shear rate (1 s^{-1}) using a rotational viscometer (RE-215U, Toki Sangyo Co., Ltd., Tokyo, Japan) and a cone-and-plate module with a 24-mm radius cone and a 1° 34′ cone angle[10, 11]. The temperature for measurements was set at 22℃. The apparent viscosity was calculated using the shear stress obtained from the following formula: $\eta = \sigma/\gamma$, where η is the apparent viscosity measured in Pa-s, σ is the shear stress measured in Pa, and γ is the shear rate measured in s^{-1}. Five consecutive measurements were taken for each sample.

The pH of gels was measured by using a pH meter (Orion STAR A211 pH, Thermo Scientific, Tokyo, Japan) and an 8302BNUMD electrode. The temperature for measurements was set at 22℃. Five consecutive measurements were taken for each sample.

Statistical analysis

The percentage removal values of the four gels were compared by one-way analysis of variance (ANOVA), and the Games-Howell method was used as a post hoc test. The Tukey multiple comparison test was used to analyze the apparent viscosity of the sample materials.

The critical value for rejecting the null hypothesis was

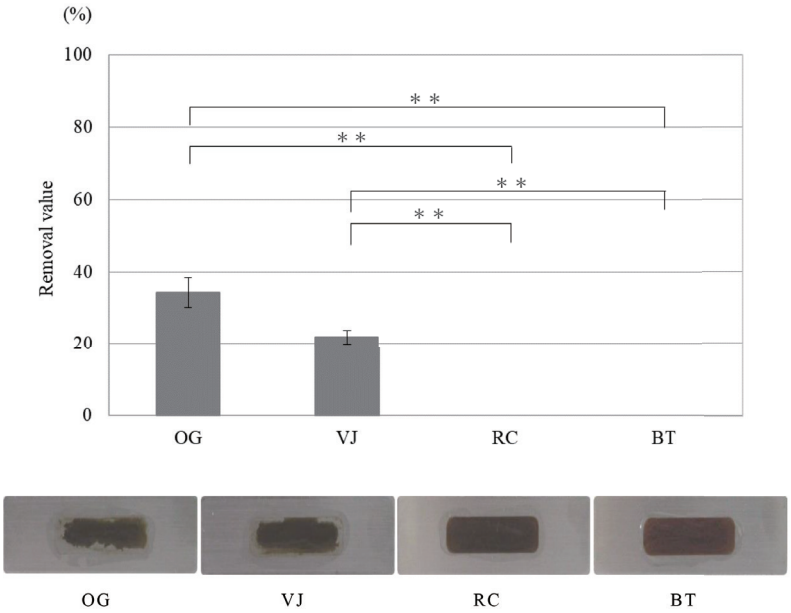

Fig. 3 Percentage removal values for the four sample gels in Experiment I.
Suction removal was performed 1 min after each gel application in Experiment I.
OG, Okuchi-Wo-Arau-Gel®; VJ, Viva-Jellwet®; RC, Refrecare®; BT, Biotene OralBalance® gel
Each material: n=19
**$p<0.01$

$p<0.05$. All statistical analyses were performed using the IBM SPSS statistics 24.0 software (IBM Japan Corp., Tokyo, Japan).

As all datasets were normally distributed according to the Kolmogorov–Smirnov normality test; thus, the use of one-way ANOVA was valid. Because the results did not exhibit homoscedasticity, the Games-Howell method was a valid post hoc test.

Results

In Experiment I, the test soil was subjected to suctioning 1 min after the application of the gel. The OG, VJ, RC, and BT had percentage removal values of 34.2 ± 4.1%, 21.8 ± 1.9%, 0.0 ± 0.0%, and 0.0 ± 0.0%, respectively. The percentage removal values for the OG and VJ were significantly higher than those for RC and BT ($p<0.01$) (Fig. 3).

When the test soil was covered with OG and VJ, a marked reduction in the amount of test soil was observed after the suctioning procedure, whereas when the test soil was covered with BT, there was little change in the amount of test soil after the suctioning procedure.

In Experiment II, the test soil was subjected to suctioning 10 min after the application of the gel. The OG, VJ, RC, and BT exhibited removal percentages of 91.7 ± 1.8%, 74.4 ± 3.7%, 40.5 ± 3.2%, and 0.0 ± 0.0%, respectively. The percentage removal value for OG was significantly higher than that for VJ, RC, and BT ($p<0.01$) (Fig. 4). In contrast to Experiment I, the OG exhibited a significantly higher percentage removal value than VJ ($p<0.05$). Figure 4 shows the percentage removal values for the OG were significantly higher than those of the other gels tested.

When the test soil was covered with OG, a marked reduction in the amount of the test soil was observed after the suctioning procedure, whereas when the test soil was covered with BT, there was little change in the amount after the suctioning procedure.

The physical properties test showed the apparent viscosities of the OG, VJ, RC, and BT were 37,372 ± 686 mPa-s, 27,520 ± 289 mPa-s, 69,002 ± 1,857 mPa-s, and 145,960 ± 3,584 mPa-s, respectively (Fig. 5).

The pH ranges of the OG, VJ, RC, and BT were pH 6.83 to 6.87, pH 6.19 to 6.21, pH 7.07 to 7.15, and pH 6.31 to 6.41, respectively, among all gels, the minimum was 6.19 and the maximum was 7.15 (Fig. 6).

Discussion

There are three potential reasons for the observed outcome: the moisture content of each sample, moisture holding capacity of the water-retaining ingredients, and formulation of the polyoxyethylene surfactant.

An apparent viscosity test was conducted to determine the moisture content of each sample. The results showed that the

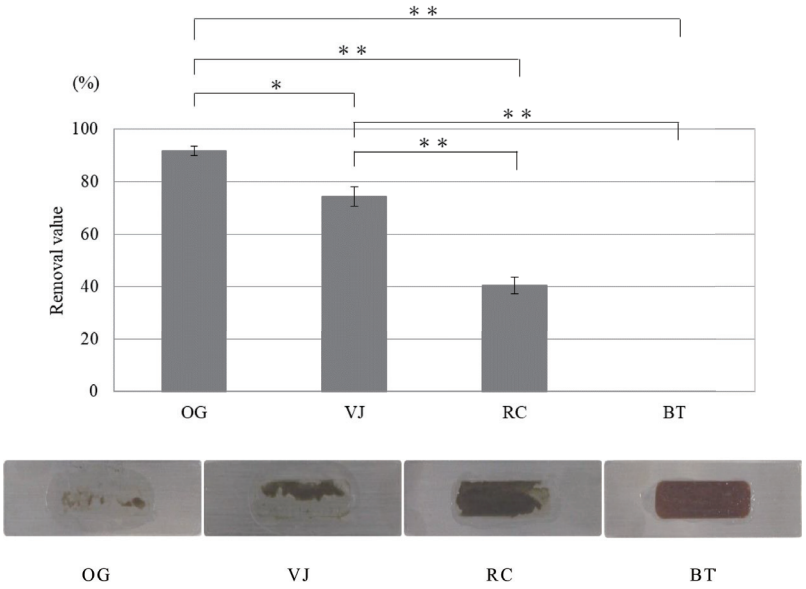

Fig. 4 Percentage removal values for the four sample gels in Experiment II.
Suction removal was performed 10 min after each gel application in Experiment II.
Each material: n=19
*$p<0.05$, **$p<0.01$

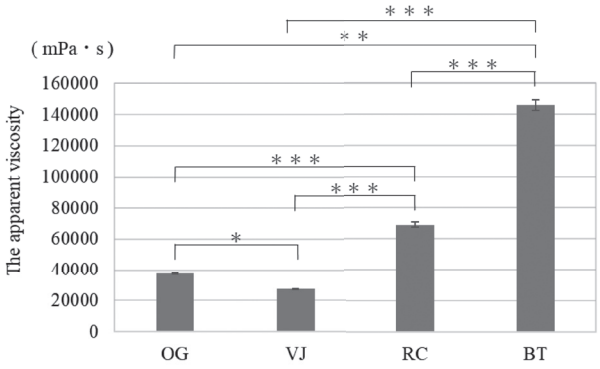

Fig. 5 Apparent viscosity of the four sample gels.
The apparent viscosity was calculated using the shear stress obtained from the following formula: $\eta = \sigma/\gamma$
Each material: n=5
*$p<0.05$, ***$p<0.001$

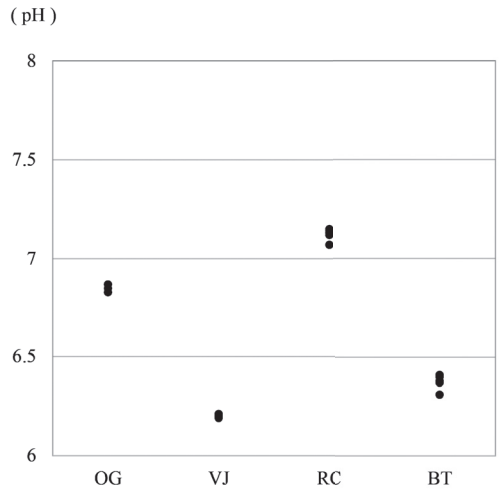

Fig. 6 pH value of the four sample gels.
The pH of gels was measured by using a pH meter and an 8302BNUMD electrode.
Each material: n=5

apparent viscosity of VJ was the lowest, followed by the OG, which was significantly lower than that of the RC and BT. This confirms that the moisture content of the VJ and OG is higher than that of the RC and BT. Thus, the higher moisture content in the VJ and OG might have allowed moisture to penetrate into the dry test soil and swell the sample, making it easier to remove, even after a 1-min application in Experiment I. Because apparent viscosity is positively related to the ability to prevent evaporation[12], it was presumed that the RC and BT with higher apparent viscosities had a higher evaporation prevention ability. RC and BT with high evaporation prevention capacity might easily retain water in the gel, making it difficult for water to penetrate the test soil. The VJ and OG, which have high moisture content, allowed water to penetrate and swell the test soil even after a short application time of 1 min in Experiment I. However, the VJ, which has low evaporation prevention ability, may have gradually evaporated during the first 10 min after application, reducing its ability to penetrate and swell the test soil in Experiment II.

This study compared the wetting and binding agents as

water retention ingredients in each sample. All samples contained glycerin. The OG and RC contained sodium hyaluronate and sodium polyacrylate, respectively, VJ contained sodium alginate, and BT contained carbomer. Sodium hyaluronate has high water retention capacity, and 1 g can retain 6 L of water[13]. Sodium polyacrylate is a polymer powder with high water absorption properties. It adheres strongly to wet surfaces and can absorb several hundred to a thousand times its own weight of water, forming a highly lubricious sol[14]. Therefore, it is expected to have an even higher moisture retention capacity. However, the sodium alginate in VJ dissolves in water to form a viscous solution, and its capillary force is responsible for its water-holding capacity[15]. In addition, the carbomer in BT is soluble in water and alcohol, and carbomer-based gels are used in dental products with a semisolid dosage form[16, 17]. The difference in water-holding capacity between the gels is likely related to the varying properties of their components. The OG has higher water content and retention capacity and absorbed water into the dry test soil even 10 min after its application. This caused the test soil to swell and lift off the stainless-steel plate, resulting in a higher removal rate than the other gels.

In relation to surfactants, the OG and RC contain PEG-60 hydrogenated castor oil, a polyoxyethylene surfactant, which is frequently used in injectable and internal liquid formulations because of its excellent solubility[18]. Surfactants affect proteins[19]. As a result, the OG, which contains PEG-60 hydrogenated castor oil, was more effective at dissolving proteins than gels without it. This may have contributed to the removal of containing proteins in the test soils.

The oral care gels tested varied in their moisture content, water retention capacity, and polyoxyethylene surfactants. It was suggested that the OG and VJ gels would be effective in infiltrating dry phlegm and debris, while the RC and BT gels would be effective in preventing persistent evaporation. It was then recommended that in oral care, the use of gels for specific purposes would be more effective than the use of randomly selected gels. However, because the study used four commercial products containing a variety of ingredients, it was not possible to determine with certainty which ingredients were involved in the removal of the test substance and to what extent.

The pH of the gel ranged from 6.19 to 7.15. Although it was reported that protein removal rates increase with higher pH levels in the alkaline range[20], we do not think that differences in the removal rates of the test soils were affected by pH in this study because even the gel with the highest pH was 7.15.

This study evaluated the efficacy of commercially available oral care gels to remove simulated dried sputum and membranous substances from human oral mucosa. Membranous substances consist mainly of oral epithelial cells, such as stratified squamous epithelium, mucus, leukocytes, and oral bacteria[21], whereas sputum is primarily composed of glycoproteins, immunoglobulins, and hydrolipids[22]. However, to objectively evaluate the removal ability of gels, the use of uniform and standardized objects was necessary because of the heterogeneous composition of the objects, which vary between and within individuals. The soil used in this study for the test soil contained albumin, hemoglobin, fibrinogen, and thrombin derived from purified bovine blood. It was homogenized to share similarities with the composition of dried sputum and membrane-like material, which is mainly composed of proteins. This allowed us to simulate testing the removal of actual dried sputum and membrane-like material.

In recent clinical practice, the recommended oral care procedure for older adult patients with impaired swallowing function involves applying oral care gel[8] to the oral mucosa with dry phlegm or exfoliated epithelium, brushing any remaining teeth while the gel penetrates the dry phlegm or exfoliated epithelium, and then suctioning out the dry phlegm or exfoliated epithelium with the gel. It is important to note that this procedure should only be performed by a trained healthcare professional. The time taken to remove the gel by suction after applying the gel ranges from 1 to 10 min, depending on the number of remaining teeth in the patient. As a result, the *in vitro* gel resting time was set to 1 min in Experiment I and 10 min in Experiment II. Because we used an *in vitro* test that simulated the removal of dry phlegm and membrane-like substances adhering to the oral mucosa, future clinical studies of patients will be necessary to establish more effective oral care.

Conclusion

This *in vitro* simulation study demonstrated the OG had a higher removal rate against test soils compared with other commercial gels. It was suggested that the OG and VJ might be more effective than other gels at removing dry phlegm and debris from the oral and pharyngeal mucosa, whereas RC and BT have better anti-evaporation properties. We think that selecting gels by purpose is one way to improve the quality of oral care.

COI statement

The authors declare no conflicts of interest.

Acknowledgments

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